

Forced-Air and a Novel Patient-Warming System (vitalHEAT vH²) Comparably Maintain Normothermia During Open Abdominal Surgery

Kurt Ruetzler, MD,* Bledar Kovaci, MD,† Elisabeth Güloglu, MD,* Barbara Kabon, MD,* Edith Fleischmann, MD,* Andrea Kurz, MD,† Edward Mascha, PhD,†‡ David Dietz, MD,*§ Feza Remzi, MD,§ and Daniel I. Sessler, MD†

BACKGROUND: The vitalHEAT vH² (Dynatherm Medical, Inc., Fremont, California) system transfers heat through a single extremity using a combination of conductive heat (circulating warm water within soft fluid pads) with mild vacuum, which improves both vasodilation and contact between the heating element and the skin surface. We tested the hypothesis that core temperatures were not >0.5°C lower in patients warmed with the vitalHEAT system than with forced air.

METHODS: Patients having general anesthesia for open abdominal surgery were randomly assigned to the circulating-water sleeve on 1 arm ($n = 37$) or an upper-body forced-air warming cover ($n = 34$). Patients were eligible to participate when body mass index was 20 to 36 kg/m², age was 18 to 75 years, and ASA physical status was 1 to 3. Intraoperative distal esophageal (core) temperatures were recorded. Repeated-measures analysis and 1-tailed t tests were used to assess noninferiority of vitalHEAT to forced air using a noninferiority δ of -0.5°C .

RESULTS: Demographic and morphometric characteristics were similar, as were surgical details. Preoperative core temperatures were similar in each group. Intraoperative core temperatures were also similar with each warming system and were significantly noninferior during the first four hours of surgery. The observed difference in means was never more than about 0.2°C. After 4 hours of surgery, the average temperature was $36.3^\circ\text{C} \pm 0.6^\circ\text{C}$ (mean \pm sd) with the circulating-water sleeve ($n = 18$) and $36.4^\circ\text{C} \pm 0.5^\circ\text{C}$ with forced air ($n = 20$), for a difference (95% confidence interval) of -0.21°C ($-0.47, 0.06$).

CONCLUSIONS: The 2 systems thus apparently transfer comparable amounts of heat. Both appear suitable for maintaining normothermia even during large and long operations. (Anesth Analg 2010;X:●●●-●●●)

Perioperative hypothermia causes adverse outcomes, including impaired drug metabolism,¹⁻³ cardiac morbidity,^{2,4-7} shivering,⁸⁻¹⁰ impaired immune function,^{6,11} coagulopathy,^{11,12} and increased use of hospital resources.^{1,13} As might thus be expected, maintaining perioperative normothermia significantly reduces morbidity^{10,12,14,15} and has become routine.

Convective (forced-air) warming is by far the most common intraoperative warming strategy. It is safe, inexpensive, and easy to use. Forced-air warming is relatively inefficient on a per-surface-area basis, but nonetheless transfers considerable heat to the anterior surface of patients because the warm air contacts a large surface area. One difficulty with forced-air warming, though, is that in patients having large procedures, especially in positions other than supine, it may be impossible to warm sufficient surface area to maintain normothermia, defined as a core temperature of 36.0°C.

Recently, Dynatherm Medical, Inc. (Fremont, California) developed the vitalHEAT vH² system that potentially transfers adequate heat through a single extremity using a combination of conductive heat (circulating warm water within soft fluid pads) with mild vacuum, which enhances contact between the heating element and the skin surface. The vH² system consists of a control unit that houses the heating system and the vacuum pump, along with a user interface and alarm management system (Fig. 1). The control system connects via an umbilical tube, containing the fluid, and vacuum tubing to the warming sleeve, which consists of a manifold attached to 2 warming pads within a polyurethane vacuum sleeve that is positioned over the patient's hand and forearm and secured with tape (Fig. 2).

Preliminary (uncontrolled and unpublished) studies suggest that the device is effective, even in open abdominal surgery. We therefore tested the hypothesis that intraoperative distal esophageal (core) temperatures are not >0.5°C lower during elective open abdominal surgery under general anesthesia in patients warmed with the warm-water sleeve on 1 arm than with an upper-body forced-air cover.

METHODS

We enrolled patients scheduled for elective major open abdominal surgery (liver, pancreas, and colon-rectal surgery) under general anesthesia scheduled to last at least 2 hours. Patients were enrolled at the Cleveland Clinic Main Campus (Cleveland, Ohio) and at the Vienna General Hospital of the

From the *Department of Anesthesia, Medical University of Vienna, Vienna, Austria; †Department of Outcomes Research, ‡Department of Quantitative Health Sciences, and §Department of Colorectal Surgery, The Cleveland Clinic, Cleveland, Ohio.

Accepted for publication April 25, 2010.

Address correspondence to Daniel I. Sessler, MD, Department of Outcomes Research, The Cleveland Clinic—P77, Cleveland, OH 44195. Address e-mail to DS@OR.org. On the World Wide Web: www.OR.org.

Copyright © 2010 International Anesthesia Research Society
DOI: 10.1213/ANE.0b013e3181e7cc20



Figure 1. The vitalHEAT controller.

Medical University of Vienna (Vienna, Austria). The IRB at each institution approved the study, and written consent was obtained from each participating patient.

Patients were eligible to participate when body mass index was 20 to 36 kg/m², age was 18 to 75 years, and ASA physical status was 1 to 3. Patients were excluded when they required bilateral vascular catheters distal to the elbow, had serious skin lesions on the hands or arms, had a history of vascular conditions including Reynaud's Syndrome, or had preoperative fever, contraindication to sevoflurane endotracheal anesthesia, or a preexisting neuropathy.

Protocol

Patients were premedicated with midazolam 0.03 mg/kg or fentanyl per clinician preference. Active prewarming was not used. Anesthesia was induced with propofol 2 to 3 mg/kg and fentanyl 2 to 3 μg/kg. Neuromuscular blocking drugs, rocuronium 0.6 mg/kg, were given and the trachea intubated. After intubation of the trachea, anesthesia was maintained with sevoflurane (minimum alveolar concentration around 1.0) and fentanyl or morphine or both. Mechanical ventilation using a semiopen circle system was adjusted to maintain end-tidal PCO₂ near 35 mm Hg. Fresh-gas flow was generally maintained at a total of 2 L/min. Intravenous fluids, mostly balanced electrolyte solution, were given at a rate of approximately 8 to 12 mL/kg/h, warmed to 40°C to 42°C.

Patients were randomly assigned to vitalHEAT (circulating-water sleeve) or forced-air warming. Randomization (1:1) was based on computer-generated codes that were maintained in sequentially numbered opaque envelopes. In patients assigned to forced-air heating, a Bair

Hugger (Arizant Medical, Inc., Eden Prairie, Minnesota) upper-body forced-air cover was positioned over the upper body and exposed arms. The forced-air blower was set to "high," which is ≈43°C, and was activated as soon as practical, usually after prepping and draping.

In patients assigned to the circulating-water sleeve, a hand and forearm without an IV or arterial catheter was inserted into the warming sleeve. The warmer was activated as soon as practical after induction of anesthesia. In most patients, the arm with the circulating-water sleeve device rested on an arm board in abduction. In a few cases both arms, including the arm with the circulating-water sleeve device, were tucked. We used cotton blankets to avoid any contact between the heating elements and the side of the body. In the initial patients, the heater was set to 42.0°C with 10 mm Hg vacuum.

The protocol was modified after 1 warm-water sleeve patient received second-degree burns after a 10-hour surgery, and another patient experienced several small blisters. The temperature for the remaining participants was set to 41°C with a 5 mm Hg vacuum. Circulating-water sleeve warming was also restricted to 4 hours, with forced-air heating being substituted at the 4-hour limit for the remaining duration of surgery.

Patients in both groups were otherwise draped per surgical routine and the upper body, including exposed arm(s), were covered with a single-layer cotton blanket. Ambient temperature was maintained near 20°C. A thermometer incorporated into a stethoscope was positioned in the distal esophagus. Rescue warming with forced air was initiated if core temperature decreased to <35°C.

Patients were examined and queried for side effects plausibly related to intraoperative warming, including erythema, bruising, limb swelling, or pain. Complications were evaluated immediately after removal of the warming sleeve, when leaving the postanesthesia care unit after approximately 2 hours, and the day after surgery.

Measurements

Demographic and morphometric characteristics were recorded. Preoperative oral temperature was measured with an electronic thermometer. Intubation was considered elapsed time zero. At 15-minute intervals thereafter, we recorded (a) distal esophageal temperature, (b) ambient temperature at the level of the patient well away from any heat-producing instruments, (c) end-tidal sevoflurane, (d) mean arterial blood pressure, and (e) heart rate.

Data Analysis

Randomized groups were descriptively compared using standard summary statistics for balance on potentially confounding baseline variables. Intention-to-treat principles were followed in that all randomized patients were included in the assigned group for analysis, even if the warming device needed to be discontinued midstream. Temperature measurements from 15 minutes after intubation until the end of the case were used for analysis.

Our primary outcome was average core temperature during surgery, with the null hypothesis that the mean temperature with the circulating-water sleeve is ≥0.5°C lower (worse) than is the mean forced-air temperature. The

Figure 2. The vitalHEAT circulating-water warming sleeve.



alternative hypothesis, which we assessed in our test for noninferiority, was that mean temperature in patients assigned to the circulating-water sleeve is at most 0.5°C lower than forced air, and perhaps higher. Our null (H0) and alternative (HA) hypotheses are thus expressed as

$$H_0: \mu_C - \mu_F \leq -0.5^\circ\text{C}$$

and

$$H_A: \mu_C - \mu_F > -0.5^\circ\text{C},$$

where μ_C and μ_F are the population means for the circulating-water sleeve and forced-air temperature groups, respectively.

We defined our δ for noninferiority to be -0.5°C , because this value has been used in previous studies and no differences in clinically important outcomes have been associated with smaller thermal perturbations. We assumed that the SD for core temperature would be 0.6°C , as has been observed in other studies. A maximum of $n = 66$ total patients was needed to show noninferiority of the circulating-water sleeve in comparison with forced-air warming on the primary outcome with 90% power at the 0.025 significance level. Because some enrolled patients inevitably have shorter operations than are anticipated, 75 patients were enrolled.

Noninferiority of the circulating-water sleeve to forced air on the primary outcome of intraoperative temperature was assessed using repeated-measures analysis (RMA) on the observed data points, testing the difference between groups against the noninferiority δ of -0.5°C in a 1-tailed test. We first assessed the effect of group (circulating-water sleeve vs. forced air), time (as both a continuous variable and a categorical variable), and the group-by-time interaction in a model adjusting for the correlation (assuming compound symmetry) among the temperature readings on the same patient.

In the absence of a group-by-time interaction, the estimated difference between groups and SE would be used to test for noninferiority with a 1-tailed t test against the a priori specified noninferiority δ of -0.5°C . In the presence of a group-by-time interaction ($P < 0.10$), group comparisons at individual time points would be made using a Holm-Bonferroni adjustment for comparing groups at hours 1, 2, 3, and 4. If noninferiority was demonstrated, as a secondary analysis we would test for superiority of 1 device versus the other on core temperature using a RMA model.

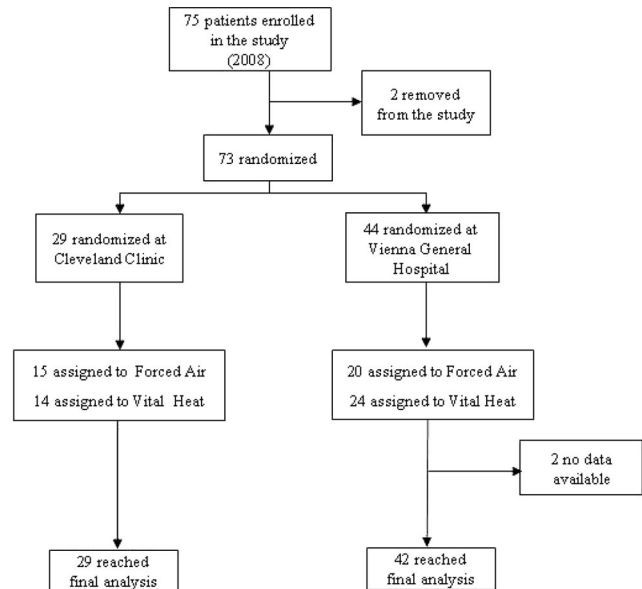


Figure 3. Trial profile.

Results are summarized as the estimated difference between treatment group means and 95% confidence interval (CI). SAS statistical software was used for all analyses.

RESULTS

Seventy-five patients were enrolled, with 73 being randomized (29 at the Cleveland Clinic and 44 at the Vienna General Hospital); however, critical data were missing from 2, bringing the total to 71. Thus, 37 circulating-water sleeve and 34 forced-air patients were included in the statistical analysis (Fig. 3). Table 1 shows demographic and morphometric characteristics of the patients in each group, along with details of anesthetic and surgical management. Hemodynamic and anesthetic variables, as well as fluid balance, were comparable in both groups. No patient required a blood transfusion.

A consequence of close contact with the heating element is that heated skin can develop impressions from the pattern of the warming pads (similar to sleep wrinkles), which generally resolve within an hour or 2 after treatment (Figs. 4 & 5). Similar stippling was observed in our patients.

The third enrolled patient was assigned to use the circulating-water sleeve and had an operation that unexpectedly lasted 10 hours. Immediately after surgery, study personnel removed the warming sleeve and noticed that

Table 1. Morphometric, Demographics and Surgical Parameters

Factor	Units	vitalHEAT (N = 37) ^c	Forced air (N = 34) ^c	P value
Age (years)	Mean (sd)	48.0 (15.5)	50.3 (15.2)	0.56
Weight (kg)	Mean (sd)	78.4 (22.6)	79.2 (21.5)	0.88
Height (cm)	Mean (sd)	172.7 (9.8)	172.5 (9.1)	0.93
Body mass index (kg/m ²)	Mean (sd)	26.1 (6.6)	26.3 (5.3)	0.89
Male	N (%)	23 (67.6)	18 (58.1)	0.42
Race				0.99 ^a
Black or African American	N (%)	1 (2.9)	1 (3.1)	
White	N (%)	32 (94.1)	31 (96.9)	
Unknown	N (%)	1 (2.9)	0 (0.0)	
Ethnicity				0.49 ^a
Not Hispanic or Latino	N (%)	34 (100.0)	31 (96.9)	
Unknown	N (%)	0 (0.0)	1 (3.1)	
ASA status				0.61 ^b
I	N (%)	5 (16.1)	2 (7.4)	
II	N (%)	21 (67.7)	21 (77.8)	
III	N (%)	5 (16.1)	4 (14.8)	
Arm tuck: left	N (%)	23 (71.9)	22 (71.0)	0.94
Arm tuck: right	N (%)	22 (68.8)	22 (71.0)	0.85
Withdrawn	N (%)	4 (11.8)	0 (0.0)	0.11 ^a
Reached ≤35°C	N (%)	3 (8.1)	4 (11.8)	0.61
Number of readings	N (%)	13.1 (3.9)	14.0 (2.9)	0.24
Preoperative temperature (°C)	Mean (sd)	36.3 (0.46)	36.3 (0.52)	0.90
Temperature at intubation (°C)	Mean (sd)	36.1 (0.31) ^d	36.2 (0.37) ^d	0.18
Measurement duration (minutes)	Mean (sd)	181 (57)	195 (43)	0.25

Statistics are presented as mean (sd) for continuous variables (t test, unless noted), and N (percentage) for categorical variables (chi-square test or Fisher’s exact test (superscript a), as appropriate). Per protocol, rescue warming was initiated at a core temperature <35°C.

^a Fisher’s exact test.

^b Mann-Whitney test.

^c N = 37 and 34, respectively, for VitalHEAT and forced air for number of readings and temperature time span, and N = 34 and N = 32 for most other variables owing to 5 patients with missing data.

^d Exception: N = 16 and N = 17 for intubation temperature.



Figure 4. Typical skin stippling immediately after removal of the circulating-water warming sleeve.



Figure 5. Typical skin stippling 2 hours after removal of the warming sleeve on the same subject.

she had a second-degree burn (blistering) covering much of her hand and forearm. Soon thereafter we noticed that a patient from the previous day, who was also assigned to circulating-water sleeve warming, also had several small blisters, although none had been present immediately after

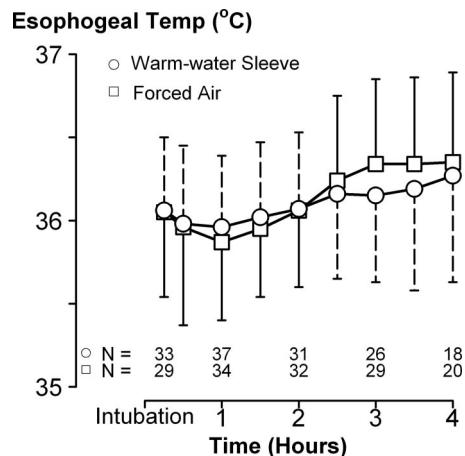


Figure 6. Core temperature as a function of elapsed time during open abdominal surgery. Intubation was considered elapsed time zero. Results shown as means ± SDs.

surgery. The smaller burn healed completely without intervention. The other was treated by a plastic surgeon and, after several weeks, healed completely without scarring.

Enrollment was stopped, and the IRB at the Cleveland Clinic and the sponsor were informed. Extensive analysis revealed that the specific circulating-water sleeve device used with these 2 patients had been incorrectly assembled by the sponsor’s Food and Drug Administration–approved contract manufacturer; specifically, the inflow and outflow tubes were inserted backwards, which resulted in the device operating at a temperature about 2°C higher than design specifications.

Table 2. Tests for Noninferiority of the Warm-Water Sleeve to Forced Air

Elapsed hour (total N: WW, FA)	Warm water Mean (SE)	Forced air Mean (SE)	Difference ^a (95% CI)	Significance	
				Criterion ^b	P value ^c
1 (71: 37, 34)	35.96 (0.081)	35.87 (0.085)	0.091 (−0.139, 0.321)	0.0062	<0.0001
2 (63: 31, 32)	36.06 (0.084)	36.09 (0.086)	−0.026 (−0.261, 0.209)	0.0083	<0.0001
3 (55: 26, 29)	36.16 (0.087)	36.37 (0.087)	−0.211 (−0.452, 0.03)	0.0125	0.011
4 (38: 18, 20)	36.25 (0.094)	36.46 (0.094)	−0.206 (−0.466, 0.055)	0.0250	0.016

FA = forced air; WW = warm-water sleeve; CI = confidence interval.

^a P value from t-test for noninferiority (delta of 0.5°C) using repeated-measures analysis (RMA) means and standard errors.

^b Holm–Bonferroni method: smallest P value criterion = 0.025/k, where k = 4 tests; next smallest criterion is 0.025/(k – 1), etc.

^c P value from RMA: all are significantly noninferior because the P values are smaller than are the given criteria.

Because the burns were thought to result from a manufacturing error rather than an intrinsic design flaw, the study was restarted with precautions that included (a) a change in device manufacturing instructions and routine inspection; (b) a reduction in operating temperature from 42°C at –10 mm Hg to 41°C at –5 mm Hg; and (c) a study case duration limit of 4 hours with circulating-water sleeve warming. Restarting the study was approved by the IRB at the Cleveland Clinic and participating surgeons; the IRB at the Vienna General Hospital (which had yet to start enrollment) was informed of the injuries at the clinic, as were all subsequent patients. In the subsequent 34 circulating-water-sleeve patients, we did not observe any cutaneous complications.

RMA with time as a continuous factor showed that temperature increased over time for the combined groups, with slope (SE) of 0.12°C (0.01°C) per hour, $P < 0.001$. The group-by-time interaction was highly significant ($P < 0.001$ for time as either a continuous variable or a categorical variable), indicating that noninferiority needed to be assessed separately at the various time points instead of overall, because the group effect was not consistent across the times (Fig. 6). Ignoring the interaction, mean core temperature was not different between groups, with an estimated mean (SE) difference of 0.037°C (0.099°C) lower in patients assigned to the circulating-water sleeve ($P = 0.71$) in a 2-tailed test for superiority. As with any nonsignificant superiority test, this result cannot be used to claim noninferiority.

Because of the group-by-time interaction, we assessed for noninferiority at 1, 2, 3, and 4 hours after start of measurements. Using the RMA model, at each time the numerator for the 1-tailed *t* test test statistic was the circulating-water sleeve mean minus forced-air mean +0.5°C, and the denominator was the SE of the difference in means. Using a Holm–Bonferroni correction for multiple comparisons, the significance criterion for the smallest to largest P values are 0.006, 0.008, 0.012, and 0.025, respectively. The observed P values from smallest to largest were $P < 0.001$ (hour 1), $P < 0.001$ (hour 2), $P = 0.011$ (hour 3), and $P = 0.016$ (hour 4). Therefore, for this primary analysis, noninferiority was detected at all 4 times, because all P values are less than the respective significance criteria. Table 2 gives these results, including the difference in means and 95% CI for each time point. The lower bound of the 95% CI for the difference between groups at each time point being above the noninferiority δ of –0.5°C corresponds to the claim of noninferiority at each time.

Because noninferiority was concluded at each time point, tests of superiority were conducted using the Holm–Bonferroni method; unsurprisingly, given the proximity of the means, no superiority was detected. The results thus indicate that the circulating-water sleeve is noninferior to forced air during surgery, defined by core temperature being no >0.5°C lower.

DISCUSSION

The efficacy of clinical warming systems depends on their ability to transfer heat to patients. For example, surgical patients are often positioned above a circulating-water mattress. Although these systems permit unrestricted access to the anterior surfaces of patients, they are inefficient warmers and the combination of heat and reduced local perfusion from the patient’s own body weight restricts capillary bloodflow, which can lead to burns and pressure-heat necrosis.^{16–18}

Recently developed systems allow circulating-water garments to cover a larger surface area of the body and thus transfer more heat than do traditional water mattresses that only heat the back and legs.^{6,14,19} Additionally, there are circulating-water systems using efficient “energy transfer” pads that transfer far more heat per square meter of body surface area than do conventional mattresses.^{20,21} However, both systems are considerably more expensive than forced air, which remains by far the most commonly used intraoperative warming system. Furthermore, most systems require contact with a fairly large body surface area. We thus evaluated a novel circulating-water system in which heating was restricted to a single hand and forearm.

Our study was designed to test noninferiority. That is, we sought statistical power for concluding that the mean core temperature for the circulating-water sleeve was no >0.5°C less than the forced-air mean. This is a far stricter test than simply showing lack of a significant difference, which often simply results from inadequate power and is the proper way of demonstrating comparable or noninferior performance. We met this goal for the first 4 hours and thus conclude that mean core temperatures for the circulating-water sleeve were significantly not lower (by >0.5°C, our a priori designated δ) than means for forced air during this period. Although the observed mean core temperature was slightly lower for the circulating-water sleeve during the later surgical period (hours 3 and 4), the lower bound of the confidence interval for the difference between methods was within the noninferiority region (above –0.5°C), mean core temperatures differed at most by about 0.2°C, and confidence intervals for the difference

were within $\pm 0.5^{\circ}\text{C}$ for the first 3 hours. Thus, there was no suggestion of any clinically important difference. We thus conclude that performance of the systems was comparable. Our results are similar to those reported by Trentman et al.,²² who found that the circulating-water sleeve system kept all but 1 of 36 patients normothermic during unilateral total knee arthroplasty; furthermore, they found that core temperature in patients warmed with the circulating-water sleeve system were only 0.4°C cooler than those warmed with forced air after 2 hours of surgery.

Heat loss is substantial during open abdominal surgery, and these patients inevitably become hypothermic without active warming. The circumstances of our study thus constituted a strict test of the heating systems. Although we did not actually quantify heat flux, it is reasonable to assume that heat transfer was comparable with forced air and the circulating-water sleeve system because core temperatures were nearly identical.

Core temperatures during open abdominal surgery were similar in patients assigned to forced air or to the circulating-water sleeve system, although the circulating-water sleeve was applied just to 1 hand and forearm. Similar clinical efficacy might appear curious because the surface area covered by the circulating-water sleeve system is only about one third of that covered by an upper-body forced-air cover with 1 arm tucked ($\approx 5\%$ vs. $\approx 15\%$ of the total).²³ However, heat transfer per square centimeter under optimal circumstances is slightly greater with circulating-water pads than with forced air.²⁴ Transfer is likely to be considerably better with a system that maintains tight device-skin contact, perhaps explaining how the smaller surface area of the circulating-water sleeve system could nonetheless transfer comparable amounts of heat.

The sleeve system with circulating water and vacuum was found to be effective. In contrast, circulating-water mattresses perform poorly.²⁵ That the circulating-water sleeve system was effective is somewhat counterintuitive because heat transfer with any given type of warming is usually a linear function of surface area, and the surface area of the back is substantial. However, there are 2 other factors to consider: insulation intrinsic to the heating system and insulation provided by skin and subcutaneous tissues.

Circulating-water mattresses, by virtue of the pressure to which they are exposed, need to be relatively thick. Although a few millimeters of plastic may seem inconsequential, it substantially impedes heat transfer. Heat flow is further impeded by the sheet that is usually present between the mattress and a patient. But heat transfer does not just depend on characteristics of the warmer; it is also limited by the ability of skin and subcutaneous tissues to absorb and dissipate heat to the rest of the body. The ability of tissues to absorb and dissipate heat is, in turn, a function of perfusion. A limitation of circulating-water mattresses is that the weight of patients compresses capillaries and reduces perfusion of subcutaneous tissues of the back, thus making the back a better insulator and reducing heat dissipation.

The circulating-water sleeve system we tested descended from a device (ThermaStat, Aquarius Medical, Scottsdale, Arizona) that reportedly increased core temperatures at the remarkable rate of $13.6^{\circ}\text{C} \pm 2.1^{\circ}\text{C}$ per hour.²⁶ The theory behind the system was that vacuum with a thermal load

would open arteriovenous shunts in the fingers and thus provide a “pipeline to the core.” Why this mechanism would be effective during anesthesia when arteriovenous shunts are already dilated by the central effects of anesthetics^{27,28} remained unclear. In fact, subsequent work with the original device showed that the system was essentially ineffective.^{29,30} The ThermaStat system used a fairly high-level vacuum in a rigid shell. The result was that tissues experienced “negative pressure” and were thus prone to edema. The important difference of the circulating-water sleeve that we evaluated is a small vacuum applied to a flexible plastic shell, which pulls the heating element towards the underlying hand and forearm. The result is a small amount of pressure on tissues that maintains good contact between the circulating-water heating element and the skin. Good contact is a critical feature of the device because even tiny air gaps are highly insulating and limit flow of heat into tissues.

The circulating-water-sleeve device that we tested also differs from the ThermaStat in another important way: the previous version used a chemical heat pack that inadequately contacted a limited amount of skin, then delivered its specified heat for only a short period before degrading. In contrast, the circulating-water sleeve uses thin-walled, low-pressure fluid pads and precisely controls both the delivered temperature and vacuum levels. The combination of a low-resistance exchange system and good skin contact proved effective.

We did not record anesthetic dosing. However, anesthetic dose is unlikely to affect outcome because even small doses of most anesthetics induce thermoregulatory vasodilation,³¹ which is the only physiological response likely to influence core temperature under the circumstances of this study.³²

Two of the 37 patients assigned to circulating-water sleeve warming were burned, although thermal injury appears to have resulted from a manufacturing defect rather than from an intrinsic design flaw. We caution, though, that our study was not powered to evaluate safety. Furthermore, the total clinical experience with the circulating-water-sleeve system was limited to <100 surgical patients at the time of our study. Additional study is thus required to confirm safety of the system, especially in patients with thin or sensitive skin, and during prolonged surgery.

In summary, mean core temperatures during 4 hours of open abdominal surgery were similar (and significantly noninferior) with the warm-water sleeve and upper-body forced-air warming. Both appear suitable for maintaining normothermia. ■■

DISCLOSURE

Supported by Dynatherm Medical, Inc. (Fremont, California). The study was designed by the investigators in collaboration with the sponsors; however, the sponsors were not involved in data collection, analysis, or interpretation of the data; the manuscript was written by the investigators, and a copy was shared with the sponsors as a courtesy.

REFERENCES

1. Lenhardt R, Marker E, Goll V, Tschernich H, Kurz A, Sessler DJ, Narz E, Lackner F. Mild intraoperative hypothermia prolongs postanesthetic recovery. *Anesthesiology* 1997;87:1318–23
2. Mort TC, Rintel TD, Altman F. The effects of forced-air warming on postbypass central and skin temperatures and shivering activity. *J Clin Anesth* 1996;8:361–70

3. Heier T, Caldwell JE, Sessler DI, Miller RD. Mild intraoperative hypothermia increases duration of action and spontaneous recovery of vecuronium blockade during nitrous oxide–isoflurane anesthesia in humans. *Anesthesiology* 1991;74:815–9
4. Frank SM, Beattie C, Christopherson R, Norris EJ, Perler BA, Williams GM, Gottlieb SO. Unintentional hypothermia is associated with postoperative myocardial ischemia. *Anesthesiology* 1993;78:468–76
5. Frank SM, Fleisher LA, Breslow MJ, Higgins MS, Olson KF, Kelly S, Beattie C. Perioperative maintenance of normothermia reduces the incidence of morbid cardiac events: a randomized clinical trial. *JAMA* 1997;277:1127–34
6. Neshar N, Uretzky G, Insler S, Nataf P, Frolkis I, Pineau E, Cantoni E, Bolotin G, Vardi M, Pevni D, Lev-Ran O, Sharony R, Weinbroum AA. Thermo-wrap technology preserves normothermia better than routine thermal care in patients undergoing off-pump coronary artery bypass and is associated with lower immune response and lesser myocardial damage. *J Thorac Cardiovasc Surg* 2005;129:1371–8
7. Neshar N, Wolf T, Kushnir I, David M, Bolotin G, Sharony R, Pizov R, Uretzky G. Novel thermoregulation system for enhancing cardiac function and hemodynamics during coronary artery bypass graft surgery. *Ann Thorac Surg* 2001;72:S1069–76
8. Cheng C, Matsukawa T, Sessler DI, Kurz A, Merrifield B, Lin H, Olofsson P. Increasing mean skin temperature linearly reduces the core-temperature thresholds for vasoconstriction and shivering in humans. *Anesthesiology* 1995;82:1160–8
9. Flacke JW, Flacke WE. Inadvertent hypothermia: Frequent, insidious, and often serious. *Semin Anesth* 1983;2:183–96
10. Kurz A, Sessler DI, Narzt E, Bakar A, Lenhardt R, Huemer G. Postoperative hemodynamic and thermoregulatory consequences of intraoperative core hypothermia. *J Clin Anesth* 1995;7:359–66
11. Michelson AD, MacGregor H, Barnard MR, Kestin AS, Rohrer MJ, Valeri RC. Reversible inhibition of human platelet activation by hypothermia in vivo and in vitro. *Thromb Haemostasis* 1994;71:633–40
12. Hofer CK, Worn M, Tavakoli R, Sander L, Maloigne M, Klaghofer R, Zollinger A. Influence of body core temperature on blood loss and transfusion requirements during off-pump coronary artery bypass grafting: A comparison of 3 warming systems. *J Thorac Cardiovasc Surg* 2005;129:838–43
13. Insler SR, O'Connor MS, Leventhal MJ, Nelson DR, Starr NJ. Association between postoperative hypothermia and adverse outcome after coronary artery bypass surgery. *Ann Thorac Surg* 2000;70:175–81
14. Neshar N, Zisman E, Wolf T, Sharony R, Bolotin G, David M, Uretzky G, Pizov R. Strict thermoregulation attenuates myocardial injury during coronary artery bypass graft surgery as reflected by reduced levels of cardiac-specific troponin I. *Anesth Analg* 2003;96:328–35
15. Kurz A, Sessler DI, Lenhardt RA. Study of wound infections and temperature group: Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization. *N Engl J Med* 1996;334:1209–15
16. Kurz A, Kurz M, Poeschl G, Faryniak B, Redl G, Hackl W. Forced-air warming maintains intraoperative normothermia better than circulating-water mattresses. *Anesth Analg* 1993;77:89–95
17. Gendron F. “Burns” occurring during lengthy surgical procedures. *J Clin Engineer* 1980;5:20–6
18. Kokate JY, Leland KJ, Held AM, Hansen GL, Kveen GL, Johnson BA, Wilke MS, Sparrow EM, Iaizzo PA. Temperature-modulated pressure ulcers: a porcine model. *Arch Phys Med Rehabil* 1995;76:666–73
19. Taguchi A, Ratnaraj J, Kabon B, Sharma N, Lenhardt R, Sessler DI, Kurz A. Effects of a circulating-water garment and forced-air warming on body heat content and core temperature. *Anesthesiology* 2004;100:1058–64
20. Grocott HP, Mathew JP, Carver EH, Phillips-Bute B, Landolfo KP, Newman MF. A randomized controlled trial of the Arctic Sun Temperature Management System versus conventional methods for preventing hypothermia during off-pump cardiac surgery. *Anesth Analg* 2004;98:298–302
21. Janicki PK, Higgins MS, Janssen J, Johnson RF, Beattie C. Comparison of two different temperature maintenance strategies during open abdominal surgery: upper body forced-air warming versus whole body water garment. *Anesthesiology* 2001;95:868–74
22. Trentman TL, Weinmeister KP, Hentz JG, Laney MB, Simula DV. Randomized non-inferiority trial of the vitalHEAT Temperature Management System vs the Bair Hugger® warmer during total knee arthroplasty. *Can J Anaesth* 2009;56:914–20
23. Sessler DI, Schroeder M. Heat loss in humans covered with cotton hospital blankets. *Anesth Analg* 1993;77:73–7
24. Sessler DI, Moayeri A. Skin-surface warming: Heat flux and central temperature. *Anesthesiology* 1990;73:218–24
25. Hynson J, Sessler DI. Intraoperative warming therapies: A comparison of three devices. *J Clin Anesth* 1992;4:194–9
26. Grahm D, Brock-Utne JG, Watenpaugh DE, Heller HC. Recovery from mild hypothermia can be accelerated by mechanically distending blood vessels in the hand. *J Appl Physiol* 1998;85:1643–8
27. Annadata RS, Sessler DI, Tayefeh F, Kurz A, Dechert M. Desflurane slightly increases the sweating threshold, but produces marked, non-linear decreases in the vasoconstriction and shivering thresholds. *Anesthesiology* 1995;83:1205–11
28. Matsukawa T, Kurz A, Sessler DI, Bjorksten AR, Merrifield B, Cheng C. Propofol linearly reduces the vasoconstriction and shivering thresholds. *Anesthesiology* 1995;82:1169–80
29. Taguchi A, Arkilic CF, Ahluwalia A, Sessler DI, Kurz A. Negative pressure rewarming vs. forced air warming in hypothermic postanesthetic volunteers. *Anesth Analg* 2001; 92:261–6
30. Smith CE, Parand A, Pinchak AC, Hagen JF, Hancock DE. The failure of negative pressure rewarming (Thermostat) to accelerate recovery from mild hypothermia in postoperative surgical patients. *Anesth Analg* 1999;89:1541–5
31. Sessler DI. Temperature monitoring and perioperative thermoregulation. *Anesthesiology* 2008;109:318–38
32. Sessler DI. Perioperative heat balance. *Anesthesiology* 2000; 92:578–96